

Editorial

The era of transcatheter closure of atrial septal defects

The morphology of the various types of interatrial communications has been known since the early description by Rokitsansky,¹ but the clinical diagnosis was not described until 1941.² Hospital mortality after surgical repair of atrial septal defects during the early years was about 3%³ and for many years it has been less than 1%, with correspondingly low complication rates. The era of transcatheter closure of secundum atrial septal defects is now well established but confusion reigns regarding ideal occlusion devices and indications for their use. The past and current success of surgery cannot be ignored when evaluating current fashions, and although it is true that routine closure is not of proved benefit to all patients there is a general consensus among cardiologists and surgeons that when an atrial septal defect gives rise to right ventricular dilatation it should be closed. Such defects usually measure 10 mm or more in diameter and occupy one third or more of the length of the atrial septum in echocardiographic four chamber sections.

Natural history

Because most defects are closed, we are unlikely ever to know the true natural history of patients with an atrial septal defect. The most detailed study available was that of Campbell in 1970,⁴ which was based on a highly selected group of patients with large and clinically obvious defects in whom actuarial survival to the age of 60 was approximately 15%, whereas in the general population it is about 85%. Few would doubt that smaller defects carry a much better prognosis. Many aspects of the natural history are well known^{4,5} and in general terms closure of these defects does benefit most patients.⁶ Survival when surgical repair is done during the first few years of life is the same as that of a matched general population. Older age at operation is a risk factor for premature late death, a risk that begins after the first decade of life and becomes progressively more powerful as age at operation increases.

Transcatheter closure

In 1976, King and Mills were the first to report the successful transcatheter closure of atrial septal defects using a double disc device introduced through a very large transvenous sheath.⁷ The pioneering work of Rashkind⁸ and Lock and colleagues⁹ provided additional evidence that similar techniques could be used effectively and with relative safety. Many of the ideas that governed these early designs have been incorporated in to devices that are now generally available for clinical use, and which offer an alternative to surgical repair in up to 70% of patients with a secundum defect. Given that surgical repair is such a safe and effective procedure, these newer techniques must be shown to have comparable outcomes to justify their continued use. The onus on all investigators is to perform controlled clinical trials with strict protocols so that results can be analysed and interpreted properly; it is important to be able to understand fully the clinical strengths and weaknesses of the various devices so that—because of the morphological and physiological variations of atrial septal defects—the best device can be chosen for an individual patient. To achieve this aim multicentre trials must

continue. Any device must achieve the goals of likelihood of complete closure with minimal risk of early or late complications. The techniques must be reasonably simple and easy to teach.

Advantages and disadvantages of the devices

The Sideris buttoned occluding device¹⁰ is made of a polyurethane foam occluder with a Teflon coated wire skeleton, which is positioned in the left atrium, and a polyurethane foam rhomboid shaped counteroccluder with a Teflon coated wire skeleton, which is positioned in the right atrium. There have been several modifications since its introduction and it is delivered through a 6–8 F catheter. Retrieval after incorrect deployment is difficult. The Cardioseal atrial septal occluder¹¹ is a modification of the original Clamshell⁹ and comprises two metal umbrella frames to which a woven polyester fabric has been attached. It is delivered through an 11 F Mullins transeptal sheath. After opening both umbrellas retrieval can be achieved only with difficulty. The atrial septal defect occlusion system (ASDOS) prosthesis¹² consists of two umbrellas made of Nitinol and a patch of porous polyurethane attached to the left and right atrial devices. It is introduced transvenously over a long veno-arterial guidewire and through an 11 F venous transeptal sheath. In the event of malpositioning before release the device is retrievable, but compared with other available devices it is more difficult to implant. In each of these three systems (buttoned, Cardioseal, ASDOS) a thin central body connects the left and right atrial devices so that, in general terms, device diameter must approach twice that of the stretched diameter of the atrial septal defect. They can all be used to close fenestrated defects of the oval fossa.

The “Angel Wings” device^{13,14} comprises two square frames made of superelastic Nitinol wire, each square frame having four legs that are interconnected by flexible islets at the corners. The wire frames are covered by polyester fabric. There is a conjoint suture ring of the right and left atrial discs, which allows self centring on deployment. The device is delivered through an 11–13 F Mullins sheath. After deployment it can be retrieved only with difficulty. An alternative self centring device is the Amplatzer septal occluder,¹⁵ which is a self expanding double saucer shaped device formed from a mesh of fine Nitinol wires with a central connecting cylinder the diameter of which is equal to that of the stretched diameter of the defect. Thrombosis following implantation is induced by three polyester patches. Delivery is through a 6–10 F Mullins sheath. Repeated retrieval and repositioning before release is achieved easily, providing a major advantage over other devices. The connecting hub of the self centring devices effectively stents the defect so that the external diameter of the device can be less than 1.5 times that of the stretched diameter of the atrial septal defect allowing larger defects to be closed than with the other systems. For example, the Amplatzer can be used to close an atrial septal defect whose stretched diameter is up to 34 mm. The Angel Wings and Amplatzer occluders, however, are unsuitable for many fenestrated defects.

Whatever device is chosen for atrial septal defect closure, the initial selection of suitable patients is based on precor-

dial echocardiography. The final arbiter of suitability is transoesophageal echocardiography, usually performed immediately before transcatheter closure. Success depends primarily on patient selection and meticulous attention to detail by a skilled and trained operator. There are many potential complications all of which have been described (Van Oort A, personal communication 1998).⁹⁻¹⁵ These include air embolism (1-3%), embolisation of thrombus formed on the device (1-2%), disturbed atrioventricular valve function (1-2%), systemic or pulmonary venous pathway obstruction (1%), perforation of the atrial wall or aorta leading to haemopericardium (1-2%), atrial arrhythmias (1-3%), and malpositioning or embolisation of the device (2-15%). Residual atrial shunts can occur in up to one third of patients and fractures of part of the metal frame supporting the fabric of the various devices is known to be a late complication.

The published data make effective comparison of the various devices extremely difficult, although it is clear that they can all be used successfully with a low incidence of major complications. The complications' inventory of the Association for European Paediatric Cardiology (Van Oort A, personal communication 1998) reveals an embolisation rate of 10% for the buttoned, angel wings, and ASDOS devices, 6% for the Cardioseal, and 0% for the Amplatzer. Most other reports include not only patients with moderate sized atrial septal defects but also those with a patent foramen ovale and some patients with extremely small defects that probably do not warrant closure. Devices other than the ASDOS can be used to close iatrogenic fenestrations following variants of the Fontan operation but this application should be considered separately. Such fenestrations or a patent foramen ovale, by nature of their small size, are much easier to occlude than an atrial septal defect.

The designers of the currently available occluding devices are to be congratulated on their ingenuity and their contribution to cardiology but none of the devices is perfect, each having their own strengths and weaknesses. The three systems with a thin central connecting body joining the left and right atrial components (buttoned, Cardioseal, ASDOS) cannot be used to close completely defects much larger than about 20 mm and frequently allow residual shunting in some patients with defects approaching this size. The buttoned device has the highest incidence of residual shunting or embolisation and, despite design improvements, the presence of only one occluding disc may explain this. Separate left and right atrial discs are probably a better option. However, the ASDOS device is the most difficult to use and is unlikely to gain universal acceptance. The Cardioseal is relatively easy to use and can be implanted successfully in many patients but has the highest incidence, so far, of late arm fractures. It remains to be seen if the recent modification to allow self centring of some of these devices proves to be of clinical value. All the devices with a wire skeleton (buttoned, ASDOS, Cardioseal, and Angel Wings) have each been known to perforate the atrial wall or aorta.

Logically the self centring devices are likely to have a lower incidence of residual atrial shunting and can be used to occlude larger defects. The Angel Wings exhibits a perfect profile and warrants design modifications that will diminish the frequency of residual shunting and embolisa-

tion. The Amplatzer device has the lowest incidence of residual atrial shunting and embolisation. Its easy retrievability before release makes repositioning after suboptimal deployment straightforward. Potential disadvantages are its relatively large bulk, the capacity for incomplete endothelialisation with thrombus formation, and the theoretical risk of nickel toxicity.¹⁶

We are well into the new era of transcatheter closure of secundum atrial septal defects and other small interatrial communications judging by the numerous recent publications in this and other journals on these topics. The modifications of existing devices and the introduction of new systems will result in current practice changing rapidly in the near future, and it is not possible to predict with any certainty which device or devices will prove to be the best during the next five years. My own preferences are the Amplatzer device for the closure of a single secundum defect because it is easy to use, can occlude large defects, and has a low incidence of residual shunts or embolisation; and the Cardioseal device for defects with multiple fenestrations in the oval fossa, for a true patent foramen ovale, and for the fenestrated atrial baffle after the total cavopulmonary connection. All investigators must provide meticulously accurate, easily understandable information with regard to success rates and complications. Only then can each patient with an atrial septal defect be offered the best treatment.

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